IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA *ex rel.* PETER HUESEMAN, Plaintiff, v. PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC., Defendant.	)	**SA-14-CA-212-XR**

UNITED STATES' RESPONSE IN OPPOSITION
TO PCCA'S MOTION TO COMPEL

The Court should deny PCCA's Motion to Compel as meritless and moot. ***First***, PCCA seeks to compel the government to supplement its Rule 26(a) disclosure on damages. The government's disclosure is more than adequate and includes detailed information about damages reasonably available to the government at this time.

Second, PCCA seeks to compel a corporate representative deposition on damages. As explained more fully in the government's Motion for Protective Order, good cause exists for the Court to quash the deposition notice because the topics depend on discovery PCCA has yet to produce. With the notice, PCCA further seeks premature expert discovery on damages. The government will designate its experts and provide their reports in accord with the Court's scheduling order. Afterwards, PCCA can depose the government's experts. In sum, PCCA can obtain the information it seeks in the notice more appropriately and effectively through expert discovery. *See* Fed. R. Civ. P. 26(b)(2)(C). And the government has already produced to PCCA substantial information that will inform its experts' assessment of damages.

Third, PCCA seeks to compel the relator's deposition. The government is not opposed to the deposition and has never sought to interfere with it. Apparently, PCCA did not even serve a copy of the deposition notice on any of the parties until June 12, 2023—after it had already moved the Court to compel the deposition.

Fourth, PCCA apparently seeks to compel the government to produce documents from Express Scripts, a third party to this litigation. As the government has previously explained to PCCA, the government is collecting, reviewing, and producing responsive, nonprivileged documents related to Express Scripts within the government's possession, custody, or control. But the government is unable to produce Express Scripts' documents outside its possession, custody, or control, including internal Express Scripts communications, Express Scripts' documents unrelated to the TRICARE program, or documents that are not a government record. Both the government and Express Scripts have separately informed PCCA that these documents must be sought directly from Express Scripts through a third-party subpoena, and Express Scripts has offered to waive service. The government understands PCCA has sent no such subpoena.

Fifth, PCCA apparently requests to file serial dispositive motions. The Court should not allow PCCA multiple bites at the apple.

LEGAL STANDARDS

Rule 26(a) requires each side to produce initial disclosures without awaiting a discovery request, including "a computation of each category of damages claimed by the disclosing party – who must also make available for inspection and copying as under Rule 34 the documents or other evidentiary material, unless privileged or protected from disclosure, on which each computation is based, including materials bearing on the nature and extent of injuries suffered[.]" Fed. R. Civ. P. 26(a)(1)(A)(iii). "A party must make its initial disclosures based on the information then

reasonably available to it. A party is not excused from making its disclosures because it has not fully investigated the case or because it challenges the sufficiency of another party's disclosures or because another party has not made its disclosures." Fed. R. Civ. P. 26(a)(1)(E).

In other words, "[a] party claiming damages has the obligation, when it makes its initial disclosures, to disclose to the other parties the best information then available to it concerning that claim, however limited and potentially changing it may be." *Tendeka, Inc. v. Glover*, No. CIV.A. H-13-1764, 2015 WL 2212601, at *16 (S.D. Tex. May 11, 2015) (internal quotation marks and citation omitted). A party must supplement its disclosure "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing[.]" Fed. R. Civ. P. 26(e)(1)(A).

"If a party fails to make a disclosure required by Rule 26(a), any other party may move to compel disclosure and for appropriate sanctions." Fed. R. Civ. P. 37(a)(3)(A). The Court has discretion to deny a motion to compel. *See Bernabe v. Rosenbaum*, No. 21-10396, 2023 WL 181099, at *4 (5th Cir. Jan. 13, 2023) (no abuse of discretion in denying motion to compel).

ARGUMENT

I. The Government's Disclosure on Damages Is More than Sufficient.

In July 2022, the government served its initial disclosures on PCCA. *See* Ex. 1, Initial Disclosures. In May 2023, the government served its first supplemental disclosure, including a revised computation of categories of damages. *See* Ex. 2, Supp. Disclosures at 3. In that computation, the government states that its damages (before trebling and penalties) could be calculated through at least three methods. *Id*.

Under the first method, "damages may be calculated by taking the difference between what TRICARE paid for each PCCA ingredient with false or fraudulently inflated" Average Wholesale Prices (AWPs) "and what TRICARE would have paid had the AWPs not been falsely or fraudulently inflated (i.e., inflated reimbursement)." *Id.* Under the second method, "damages for FCA violations based on underlying AKS violations may be calculated by taking the full amount TRICARE paid within a claim for each PCCA ingredient with inflated AWPs (i.e., the entire amount for each inflated PCCA ingredient within a tainted claim)." *Id.* And under the third method, "damages may also be calculated by taking the entire amount TRICARE paid for each claim that contained a PCCA ingredient with inflated AWPs (i.e., the entire amount of the tainted claim)." *Id.*

The government then adds, "For the period from March 2012 through May 2015, the United States estimates that TRICARE paid several hundreds of millions of dollars for the [ten] ingredients and [three] bases identified as illustrative examples in paragraph 61 of the United States' Complaint and included in compound prescription claims submitted to TRICARE." *Id.* at 4. But the government cautions that "PCCA's fraudulent AWP pricing and kickback scheme was not limited to these examples[]" and, as the complaint alleges, "extended across the board to many other PCCA ingredients and bases." *Id*.

The government provides a chart reflecting "a preliminary estimate of the amount TRICARE paid for" twenty PCCA ingredients or bases, including the ten ingredients and three bases highlighted in the government's complaint as illustrative examples:

NDC	INGREDIENT/BASE	TRICARE AMT PD (IN MILLIONS)
51927433000	FLUTICASONE PROP MICRO POWDER	175.3
51927421300	GABAPENTIN POWDER	123.8
51927448200	PCCA CUSTOM LIPO-MAX CREAM	79.4
51927465500	PRACASIL TM-PLUS GEL	77.5

51927279000	KETAMINE HCL POWDER	56.4
51927270100	FLURBIPROFEN POWDER	50.3
51927170500	HYALURONIC ACID SOD SALT POWD	47.8
51927333800	PCCA LIPODERM BASE	37.6
51927436700	RESVERATROL POWDER	34.7
51927250100	CYCLOBENZAPRINE HCL POWDER	25.7
51927200700	BACLOFEN POWDER	18.2
51927467800	BASE, PCCA SPIRA-WASH GEL	13.2
51927461500	NABUMETONE MICRONIZED POWDER	11.9
51927235800	BUPIVACAINE HCL POWDER	11.2
51927185900	DICLOFENAC SODIUM POWDER	10.2
51927465400	LEVOCETIRIZINE DIHYDROCHL PWDR	8.5
51927172000	PRILOCAINE HCL POWDER	5.9
51927480200	SUMATRIPTAN SUCCINATE POWDER	5.6
51927438900	PENTOXIFYLLINE POWDER	2.3
51927121300	LIDOCAINE HCL POWDER	2.1

Id.

The government explains that PCCA's alleged wrongdoing "caused TRICARE to pay excessive reimbursement for PCCA ingredients included in tens of thousands (and possibly hundreds of thousands) of fraudulently inflated claims." *Id.* at 5. The government maintains that "[t]he number of ingredients at issue, the number of false claims at issue, the damages sought by the United States, the measure and/or computation of those damages, as well as other related issues, are matters to be considered by our experts and addressed in expert reports." *Id.* The government makes clear that it "will provide PCCA with its expert report(s) calculating the damages to TRICARE for the ingredients at issue in this case by the date set forth in the scheduling order." *Id.* And it "intends to produce to PCCA claims data for compound prescription drugs submitted to TRICARE containing at least one PCCA ingredient for the time period January 1, 2012 to May 31, 2015." *Id.* The government provided this claims data to PCCA on June 12. *See* Ex. 3, Transmittal Ltr.

The government lastly notes, "Identifying all PCCA ingredients at issue (beyond the ingredients identified above) and the resulting number of false claims at issue will also depend

upon discovery the United States has propounded on, but that has not yet been produced by, PCCA[,]" namely "PCCA's AWP pricing and promotional policies and practices, complete invoice information for PCCA ingredients sold to PCCA customers, and the amounts PCCA paid to acquire its ingredients from other manufacturers and/or suppliers." *See* Ex. 2, Supp. Disclosures at 5. Accordingly, the government reserved the right to include additional ingredients and bases and supplement its disclosure. *Id.* 5-6.

This disclosure on damages is more than sufficient under Rule 26(a) because it includes the government's detailed computation of each category of damages based on information reasonably available to it at this time—"however limited and potentially changing it may be." *Tendeka*, 2015 WL 2212601, at *16; *see also Henry's Marine Serv., Inc. v. Fireman's Fund Ins. Co.*, 193 Fed. App'x. 267, 278 (5th Cir. 2006) (affirming district court's finding that plaintiff's disclosure —though "not perfect"—"was not a failure to disclose", where the disclosure identified categories of expenses, but could not identify "an exact amount of damages."); *Monocoque Diversified Interests, LLC v. USA Jet Airlines, Inc.*, No. A-21-CV-00956-RP, 2022 WL 2919350, at *2 (W.D. Tex. July 25, 2022), *report and recommendation adopted*, No. 1:21-CV-956-RP, 2022 WL 17732699 (W.D. Tex. Aug. 24, 2022) (denying motion to compel amended initial disclosures on damages, where plaintiff claimed $12 million in damages and defendant claimed the damages were improperly based on claims no longer in the case).

The government's disclosure here is easily distinguishable from the disclosure cited by PCCA in *Hovanec v. Miller*, 331 F.R.D. 624, 629 (W.D. Tex. 2019), which merely stated, "The Plaintiff is seeking damages that are still being calculated." The Court should therefore deny PCCA's Motion to Compel on this point.

II. PCCA's Contentions about the Disclosure are Unavailing or Irrelevant.

PCCA maintains that the disclosure is insufficient because it fails to disclose: (1) the number of claims at issue; (2) how the government chose the claims; (3) which ingredients and bases are at issue; (4) the maximum damages sought; (5) the method for calculating damages; and (6) whether the government will use a sample and extrapolation. Dkt. 118 at 8. But, as explained in detail above, the disclosure provides information on most of these issues. The universe of claims at issue are those that contain at least one PCCA ingredient for the time period January 1, 2012 to May 31, 2015—the period in which PCCA's alleged wrongdoing occurred. PCCA has the claims data for those claims, including information on the ingredients and bases. And the government specified three possible methods it may use to calculate damages.

PCCA cites no authority requiring the government at this point in the litigation to specify the maximum damages it seeks or to disclose whether it will use a sample. These are matters on which the government's experts will opine. Tellingly, the one case PCCA cites addresses an expert's opinion, not the sufficiency of the plaintiff's initial or amended disclosure. *See United States v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *11-12 (N.D. Tex. June 20, 2016) (considering sample in context of a motion to strike an expert's opinion).

Next, PCCA contends that the disclosure is inconsistent with prior representations made by the government, limiting damages to ten ingredients during the Motion to Dismiss hearing. Dkt. 118 at 3. The transcript from the hearing reads in relevant part:

> The Court: So I understand that, but when we are talking about a billion dollars too and the proportionality analysis, that's quite a large amount in controversy.
>
> [Government's Counsel]: Again, Your Honor, I do want to make clear, that is not what we are claiming as the amount of damages. That was the amount that TRICARE ended up paying, and we're focusing on a much narrower subset of claims. And we're focusing on -- and that's what we've tried to do in our complaint, focusing on the ten ingredients that had the most egregious AWP spreads. So we're not going after every single item or claim.

> And we've also identified, in terms of the examples, claims that were between $2,000 and above. It's not every ingredient.
>
> The Court: Yeah. So let's try to -- if that's going to be your contention here how you are going forward, let's just make that clear so discovery is limited to those issues. And then while you-all are talking we all know what to focus in on the numbers regarding those issues.
>
> [. . . .]
>
> [PCCA's Counsel]: So first is the government's position then that they are limiting their claim for damages to the ten ingredients listed in the complaint?
>
> The Court: That's a good question, because is it ten or two? Who wants to answer?
>
> [Government's Counsel]: Your Honor, we focused on the ten ingredients. We've identified ten ingredients, and those ingredients themselves involve -- would produce overpayments of, you know, over $100 million. Now, Your Honor, again, we're not talking about every single ingredient but we are willing to focus our complaint and we have limited our complaint to the ten ingredients.
>
> [. . . .]
>
> The Court: Thank you. So ten ingredients, TRICARE.

6/16/2022 Tr. at 21-23.

Out of the hundreds of products PCCA sold, the government's complaint identified ten PCCA ingredients and three bases as "examples" that are "illustrative" of PCCA's inflated AWPs in relation to their selling prices and alleged that "PCCA's scheme extended broadly to many other ingredients as well." Dkt. 66 at ¶62. Further, the complaint traced the increase in AWPs for two specific ingredients—fluticasone propionate and resveratrol—between 2012 and 2015. *See id.* at ¶¶122-140. These two examples served "[t]o illustrate the effects of PCCA's AWP increases and marketing efforts[.]" Dkt. 109 at 8.

At the Motion to Dismiss hearing, when the Court asked whether damages were limited to "ten or two," the government's counsel responded with the larger number. By referring to "10 ingredients," however, the government's counsel did not intend to exclude the 3 PCCA bases it identified in the complaint or to limit discovery to just 10 ingredients, but to reassure the Court that it was not seeking damages on "every single ingredient." The government should have further

clarified what it explicitly stated in the complaint: that the ingredients and bases listed in paragraph 61 are "examples" that are "illustrative" of PCCA's scheme. Dkt. 66 at ¶62. The government has made this point clear to PCCA repeatedly in letters and during "meet and confer" conferences in response to PCCA's efforts to limit the government's discovery to documents that explicitly reference those ingredients. *See*, *e.g.*, Ex. 4, 1/20/2023 Ltr. at 4-6. PCCA has suffered no prejudice or surprise.

The government reiterates that it does not intend to seek damages on every PCCA ingredient or base. The government intends to select a precise number of ingredients and bases (including those highlighted in the complaint) for which it will seek damages at trial. But that selection depends on documents yet to be produced by PCCA and evaluated by the government and its experts. This discovery includes, but is not limited to, communications between PCCA sales personnel and PCCA customers, complete invoice information as to the net prices PCCA's customers paid for its ingredients and bases, and the net prices PCCA paid to manufacturers and vendors to acquire these ingredients.

Regardless, even if damages were limited to specific ingredients, that limitation would not make the government's disclosure insufficient under Rule 26(a) or limit discovery to only documents that explicitly reference those ingredients. Because the government's complaint alleges a fraudulent AWP pricing and marketing scheme with particularity under Rule 9(b), *see* Dkt. 109 at 16-17, the government is entitled to "discovery on the entire fraudulent scheme." *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750, 768 (6th Cir. 2016) (internal quotation marks omitted); *see also United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 191 (5th Cir. 2009) ("[w]hile Rule 9(b) stands as a hurdle preventing discovery when a complaint fails to sufficiently define its claims, it does not do away with

discovery altogether by allowing access to discovery only when the complaint already contains all the information necessary to succeed at trial.").

PCCA further takes issue with paragraph 45 of the government's complaint. Dkt. 118 at 6. The paragraph provides a general summary of the "lesser of logic" applicable to TRICARE's reimbursement of compound prescription claims:

> During the relevant time period, TRICARE generally reimbursed compound prescription claims based on of the lesser of the following amounts: (1) the sum total of the AWPs (minus a contracted discount) for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; (2) the sum total of the costs submitted by the pharmacy for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; or (3) the pharmacy's usual and customary charge for the medication. The reimbursement amount was also based on the quantity of each ingredient in the compound. Under this methodology, the reimbursement for compound prescription claims submitted to TRICARE by PCCA customers was frequently determined by the reported AWPs.

Dkt. 66 at ¶45. PCCA contends that the government lacks evidentiary support for the phrase "the sum total of the costs submitted by the pharmacy for all ingredients in the compound drug." *See* Dkt. 118 at 6.

PCCA's contention is irrelevant to whether the government's damages disclosure is sufficient. Moreover, the contention is incorrect because there is evidentiary support as the government explained to PCCA's counsel in April 2023. *See* Ex. 5, 4/12/2023 Email. For instance, in the 2013 Network Provider Manual, Express Scripts states that it would pay the lesser of, among other things, "AWP ingredient cost[;]" "submitted brand ingredient cost[;]" or "Usual and Customary Retail Price[.]" *See* Ex. 6, Excerpt from 2013 Network Provider Manual at 17-18 (filed under seal). And the Manual goes on to state: "The Ingredient Cost Submitted field . . . in the Pricing Segment must equal the sum of the Compound Ingredient Drug Cost . . . for each ingredient." *Id.* at 21.

The government understands that the "lessor of logic" referenced in the Manual applied to compound prescriptions. PCCA did too. In a presentation produced by PCCA, it states, "The final

adjudicated price shall be the lesser of: a) Usual and customary price b) Submitted final ingredient cost + LOE c) Total allowable ingredient cost[.] Dispensing fess and discounts off AWP apply to b and c[.]" Ex. 7, PCCA Presentation at 52 (filed under seal).[1]

In its Motion, PCCA equates "acquisition costs" with "the costs submitted by the pharmacy." *See* Dkt. 118 at 6. As the government has previously noted, the complaint does not allege that PCCA's customers submitted their "acquisition costs" in their compound claims. *See* Dkt. 91 at 55. And the complaint does not allege that "the costs submitted" means acquisition costs. If PCCA's customers had submitted their true acquisition costs as "the costs submitted" in their compound claims, TRICARE would have paid based on that amount under the lesser-of-logic because they were far lower than PCCA's AWPs. The complaint, however, alleges that PCCA advised its pharmacy customers not to disclose PCCA's selling prices or the pharmacy's acquisition costs to auditors. Dkt. 66 at ¶¶153-57.

PCCA contends that the government's claims depend on the premise that "the Government actually paid claims based on 'acquisition costs.'" Dkt. 118 at 7. Not so. The government alleges violations of the FCA, AKS, and common law based on PCCA's inflated AWPs and marketing of the spread between the AWPs and its selling prices to the pharmacies. Dkt. 66 at ¶¶1-16. Critically, even if PCCA is correct—which the government strongly disputes—PCCA's

[1] Contrary to PCCA's assertions (Dkt. 118 at 10), the relator's complaint explains the "lessor of logic" in substantially the same way as the government: "[Federal Health Care Programs and private plans] generally reimburse claims at the lower of the following amounts: (a) The ingredient cost, plus the applicable level of effort/dispensing fee; (b) The plan sponsor-specific reimbursement, plus the applicable dispensing fee; or (c) The pharmacy provider's reported U&C. As the basis for pricing ingredient cost when adjudicating a compound product Claim, historically and up to the present, FHPs and private plans have relied on and used the unadjusted Average Wholesale Price[.]" Dkt. 1 at ¶¶81-82.

contention goes to whether the United States can prove its case, not whether the government's damages disclosure is sufficient.

III. The Government Did Not Interfere with Relator's Deposition.

PCCA seeks to compel the deposition of the relator, claiming that it "issued a Notice of Deposition[]" to him and that "DoJ counsel has apparently precluded that [deposition] from happening." Dkt. 118 at 4, 10. The government is not opposed to the deposition and has never sought to interfere with it. Apparently, PCCA did not even serve a copy of the deposition notice on any of the parties until June 12, 2023—after it had already moved the Court to compel the deposition. *See* Dkt. 120 at 1; Ex. 8, Dep. Notice of Relator at 3. Regardless, because the relator's counsel has agreed to present him for deposition, this issue is moot.

IV. The Government Is Producing Responsive, Non-Privileged Documents related to Express Scripts in Its Possession, Custody, or Control.

PCCA seeks "a candid discussion of what, if anything, Government counsel can do to facilitate reasonable discovery from its agent Express Scripts, Inc. [ESI], which is apparently also represented by counsel." Dkt. 118 at 11 (emphasis omitted). The government has informed PCCA of its position on this issue several times. *See*, *e.g.*, Ex. 4, 1/20/2023 Ltr. at 12. Namely, the government is collecting, reviewing, and producing responsive, nonprivileged documents related to Express Scripts within the government's possession, custody, or control. By way of example, the government has already produced Express Scripts' Network Provider Manuals; the TPharm contracts with Express Scripts along with all modifications, TRICARE claims data collected from Express Scripts, and an initial production of communications between Express Scripts personnel and the Defense Health Agency. The government has been making rolling productions of those communications and plans to make another production this week.

The government, however, is not collecting internal Express Scripts communications, Express Scripts documents that are unrelated to the TRICARE program, or documents that are not a government record. Express Scripts has informed the government that any such documents are not within the government's possession, custody, or control and must be sought directly from Express Scripts, a third party to this litigation, through appropriate legal process like a subpoena. *See* Fed. R. Civ. P. 45.

Additionally, about two weeks ago, counsel for Express Scripts informed PCCA that it would need to send Express Scripts a subpoena. And on June 9, 2023, counsel for Express Scripts reiterated the point and told PCCA that Express Scripts would waive service of process. *See* Ex. 9, 6/9/2023 Email. Like the deposition of the relator, the government has not impeded PCCA from obtaining documents from Express Scripts. PCCA has simply failed to seek the discovery through the appropriate legal process.

V. The Court Should Not Allow PCCA to File Serial Motions for Summary Judgment.

PCCA appears to request that the Court permit it to file "an early dispositive motion focused on a narrow issue or two without prejudice to a later, more comprehensive filing." Dkt. 118 at 12. If PCCA wants to file a motion for summary judgment earlier than the deadline in the scheduling order, PCCA may do so. But PCCA should not be able to file serial motions for summary judgment. *See Calvasina v. Wal-Mart Real Estate Bus. Tr.*, 899 F. Supp. 2d 590, 621 (W.D. Tex. 2012) ("The Court finds that Defendants' motion to supplement should be denied and the successive motion for summary judgment on this issue should be stricken because Defendants provided no valid excuse for failing to raise this argument or present this evidence previously.").[2]

[2] PCCA maintains that it "reluctantly agreed to extend the date for trial from November 2023 until May 2024[.]" Dkt. 118 at 5. PCCA expressed no such reluctance to the Court in the parties' joint motion to extend the deadlines in scheduling order. *See* Dkt. 107 at 3.

CONCLUSION

For the foregoing reasons, the Court should deny PCCA's Motion to Compel.

Dated: June 13, 2023.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on June 13, 2023, I served the foregoing document and the proposed order via CM/ECF on all counsel of record registered to receive CM/ECF notifications.

/s/ John M. Deck
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